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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,158	05/14/2001	Lars Eyde Theill	A-686A	8931

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AMGEN INCORPORATED  
MAIL STOP 27-4-A  
ONE AMGEN CENTER DRIVE  
THOUSAND OAKS, CA 91320-1799

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/06/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p>09/855,158</p>	<p>Applicant(s)</p> <p>THEILL ET AL.</p>	
	<p>Examiner</p> <p>Karen A Canella</p>	<p>Art Unit</p> <p>1642</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

1. Claims 13, 16 and 17 have been amended. Claims 1-17 are pending. Claims 1-12 remain withdrawn from consideration. Claims 13-17 are under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13 is drawn to a composition of matter, wherein neither X1 nor X2 is a native protein. The response does not indicate by page and line number where support can be found in the specification for this amendment. It is noted that the specification contemplates muteins defined as conservative or non-conservative modification of the amino acid sequences of peptides and fusion peptides of the invention (page 34, lines 9-12). However, the contemplation of muteins does not provide support for the instant amendment which specifies that the "X" groups, although composed of the consensus regions of TACI, BCMA and the TACI/BCMA extracellular consensus sequences must not be a native protein. The claim reads on "X" groups comprising denatured consensus regions of TACI, BCMA and the TACI/BCMA extracellular consensus regions. Thus, it can be reasonably concluded that the claims are not drawn to compositions comprising muteins, because a protein which comprises a variant protein does not comprise the protein itself. Therefore claims drawn to a composition which comprises a consensus sequence excludes compositions which comprise variants of the same consensus sequence. One of skill in the art would reasonably conclude that applicant was not in possession of the invention at the time of filing.

4. Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

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the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 13 has been amended to recite a composition of matter, wherein neither X1 nor X2 is a native protein. Claim 13 specifies that "X" is selected from the consensus region of TACI, the consensus region of BCMA and the TACI/BCMA extracellular consensus sequence. Claim 16 embodies the composition of claim 14, which is dependent on claim 13. Claim 16 recites the limitation wherein one of P1 or P2 is a specific binding partner for AGP-3 and APRIL. The limitation of claim 13, wherein P1, 2, 2 or 4 is independently selected from the consensus region of TACI, the consensus region of BCMA and the TACI/BCMA extracellular consensus sequence excludes variants of said consensus regions and extracellular consensus sequences. Given this limitation as to what P1-P4 must comprise, the further limitation that the native protein be excluded from the composition reads on the denatured consensus region of TACI, the denatured consensus region of BCMA and the denatured extracellular consensus sequence TACI/BCMA because the denatured forms of these consensus sequences will comprise the same amino acid sequence as the native forms. It is recognized in the art that ligands must possess significant structural and chemical complementarity to their target receptors (Kuntz et al, Science, 1992, Vol. 257, pp. 1078-1082, especially page 1079, second column, lines 1-4 and 9-12 under the heading "Structure-Based Design) and that ligands generally bind to native states of proteins with little or no interaction with unfolded states (Miller et al, Protein Science, 1997, Vol. 6, pp. 2166-2179, especially page 2166, second column, lines 18-20) and further that alterations in protein structure lead to alterations in binding affinity proportional to the magnitude of the alteration (Miller et al, abstract, lines 2-4). The claims encompass alterations in protein folding because the claims do not permit deviation from the amino acid sequences of the consensus regions for a non-native protein. It would be reasonable to conclude that alterations in protein folding would lead to a large alteration in binding affinity. The specification does not teach how to make such a composition comprising denatured receptor sequences which would retain binding affinity for the APRIL or AGP-3 ligand, nor does the specification teach a use for the composition comprising the denatured proteins apart from binding to APRIL or AGP-3 ligand. Given the lack of teachings or examples regarding the above issues, one of skill in the art would be subject to undue experimentation.


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5. All other rejections and objections as set forth in Paper No. 12 are withdrawn in light of applicants amendments.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

10/27/03